

### Comments

The new claims are presented to better define the present invention in the context of a nutritional or dietary supplement that is fixed and maintained in a form for long term storage. Although the references cited by the Examiner in the last action, for example the Lynn, Gelinas, and Spiller et al patents relied upon by the Examiner for the Section 102 rejections, disclose bacteria, yeasts and proteins, these references do not disclose such combinations formulated and maintained as solid, dry, admixed compositions for use as a nutritional supplement. Thus, the newly presented claims specifically recite that the compositions are a “solid, dry, granular admixture” and specify that the admixture is maintained in a “sealed, airtight container” to preserve the beneficial health properties.

The references cited do not propose such a dry, granular admixture and container combination because the practical teachings of Lynn, Gelinas and Spiller et al are limited to the breadmaking technology described therein. Note for example the following passage in Lynn USP 5,185,165. Rather than forming a dry, solid, granular admixture as in the new claims, not surprisingly, Lynn formulates a composition as a slurry for use in combining the components of a dough:

The present invention provides, in particular, an active ferment concentrate comprising yeast, water and a novel precursor base. The precursor base comprises an acidic concentrate, at least one type of sugar, yeast, at least one type of flour, non-fat dry milk, and at least one type of lactic acid producing bacteria. The precursor base is prepared by combining the acidic concentrate with a portion of the total sugar to be used in making the precursor base to form a liquid composition for slurry. In a separate step the lactic acid producing bacteria is diluted with a small amount of flour. In yet another separate step, the other ingredients, that is, the remaining portions of flour and sugar, the non-fat dry milk, the flour-bacteria dilute and the

yeast are combined and thoroughly blended together. During this blending step the liquid compositions or slurry is added to the combined ingredients. In a preferred embodiment, the ingredients of the precursor base are present in the following ranges, by weight percent of the total precursor base: acidic concentrate 1.2-2.0 wt. percent; sugar 5.0-20.0 wt. percent; yeast 0.5-1.5 wt. percent; flour 65.0-85.0 wt. percent; non-fat dry milk 4.0-8.0 wt. percent; and lactic acid producing bacteria approximately  $5^5$ - $15^5$  organisms/grams.

The differences between the compositions of the Lynn reference and the compositions recited in the newly presented claims are also demonstrated by the apparatus and methodology described in Lynn for the mixture of the water, yeast, and the "precursor base":

The present invention also provides an apparatus which includes a precursor system containing an agitator means which blends the precursor base, water and yeast. After multiple incubations in the precursor system, a finished precursor slurry or active ferment concentrate is produced. The precursor slurry is pumped to a fermentor system which includes an impeller means which blends the precursor slurry with 15% of flour, water, yeast, yeast nutrients and sugar. The impeller means thoroughly mixes the precursory slurry, water, flour, yeast, yeast nutrients and sugar to form a preferment mixture. The preferment mixture is allowed to ferment. When the fermentation cycle has been completed the preferment mixture can be easily and quickly pumped through a heat exchanger where heat is transferred from the preferment mixture so that the preferment mixture achieves the desired temperature. In addition, the preferment mixture can be passed from the heat exchanger into a holding tank system prior to use in preparing the bakery product dough.

For obvious reasons, Lynn does not disclose maintaining a "solid, dry, granular admixture" in a "sealed, airtight container," as is expressly recited in the new claims, because such a composition and container would be contrary to the stated purposes of Lynn of forming a dough for baking purposes.

Similarly, the Gelinas patent is directed exclusively to the bakery arts and does not teach the container and dry, granular admixture of the new claims. The specific Examples in the Gelinas

patent cited by the Examiner for the section 102 rejections demonstrate this fact. Each of Examples 1, 2 and 5 use 1000 ml of water in a mixing process; Example 4 specifies a “variable” amount of water. Thus, the composition recited in the new claims does not exist in the Gelinas reference.

The passages in the Spiller et al reference cited by the Examiner further illustrate the infirmity of the prior art relative to the newly presented claims. The bridging paragraph from columns 11 to 12 illustrates that the typical formulation of Spiller et al contains significant water, as does Example 2. Although dry compositions of various components i.e., yeast, lactobacillus, and proteins are made transiently in the cited references, none maintain a dry admixture in a sealed container as the final product, and, thus, none establish a basis for rejecting the new claims under 35 U.S.C. § 102.

Under § 103, as a threshold issue, none of the Lynn, Gelinas or Spiller et al references can properly be combined with references such as Friend et al to form a rejection of applicants’ newly presented claims under 35 U.S.C. § 103. Each of these references are non-analogous art because the respective disclosures are not “reasonably pertinent to the particular problem with which the inventor was involved.” See Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1535, 218 U.S.P.Q. 871, 876 (Fed. Cir. 1983) quoting In re Wood, 599 F.2d 1032, 1036, 202 U.S.P.Q. 171, 174 (CCPA 1979).

Thus, any combination that includes the Lynn, Gelinas, or Spiller et al references, for example in combination with the Jolly or Friend et al references, is not a proper combination. No evidence of record exists to suggest that one of ordinary skill in the art would look to bakery formulations or process technology to overcome storage limitations for bacteria-containing

nutritional supplements as in the present invention. Moreover, as demonstrated in the discussion of § 102 above, even if the combinations were made, a prima facie case of obviousness does not exist for the newly presented claims because necessary elements of the claims are not disclosed in the cited references.

Interestingly, when read in the proper context, the Friend et al reference supports the novelty and patentability of the invention defined by the new claims because Friend et al actually demonstrates the difficulty in formulating a lactobacilli bacteria-containing product for dietary use. Friend et al state the following at page 133 to 134:

Firstly, the benefits associated with one particular strain of lactobacillus may not necessarily apply to all other strains of the same organism. For example, screening studies in our laboratory showed that *L. acidophilus* DDS 1 produced the natural antibiotic acidophilin; no other strain of *L. acidophilus* tested produced significant quantities of this metabolite. Since the ability to survive and implant in the intestine or the synthesis of certain enzymes or metabolites is normally strain specific, care must be taken in ascribing beneficial properties to strains of lactobacilli which have not been properly evaluated in the laboratory.

Secondly, commercial preparations of cultures shown to be effective in the laboratory may not contain sufficient viable organisms to be of any benefit. Specialized media and techniques are required to handle, propagate and concentrate the lactobacilli to ensure that adequate numbers of viable organisms survive the concentration, freezing, freeze-drying or drying process needed to prepare a shelf-stable commercial product. Certain strains may be more amenable to these processes than others. Also, care should be taken in handling products during storage and distribution to avoid loss in viability.

(emphasis added.)

Therefore, amongst the cited references, Friend et al teaches and demonstrates the difficulty in formulating a lactobacillus bacteria-containing product for commercial use. While Friend et al

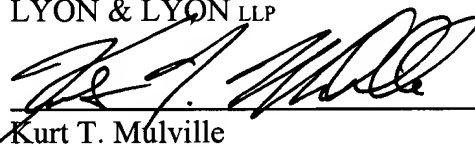
note the difficulty, Friend et al make no suggestion as to how to overcome the shelf-life issue. Lynn, Gelinas, and Spiller et al are directed to a completely different application and never formulate the specific composition of the claims. Thus, applicants' claimed invention overcomes the limitations noted by Friend et al, using a composition not taught or suggested by the other references of record. On this basis, Applicants submit that the new claims are in condition for allowance and request such action accordingly.

Respectfully submitted,

LYON & LYON LLP

Dated: January 19, 1999

by:



Kurt T. Mulville  
Reg. No. 37,194

KTM:lf  
633 West Fifth Street, Suite 4700  
Los Angeles, California 90071-2066  
(714) 751-6606, Ext. 1124